UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC, *Plaintiffs*, v. WATSON LABORATORIES, INC. - FLORIDA, *Defendant.*	Civil Action No.: 11-5989 (FSH)(PS)
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC, *Plaintiff*, v. TEVA PHARMACEUTICALS USA, INC., *Defendant.*	Civil Action No.: 11-6936 (FSH)(PS)
WARNER CHILCOTT COMPANY, LLC and WARNER CHILCOTT (US), LLC, *Plaintiff*, v. RANBAXY, INC, and RANBAXY LABORATORIES LIMITED, *Defendant.*	Civil Action No.: 12-2474 (FSH)(PS)

DEFENDANTS' RESPONDING BRIEF
IN FURTHER SUPPORT OF THEIR
PROPOSED CLAIM CONSTRUCTIONS FOR
U.S. PATENT NOS. 7,645,459, 7,645,460, AND 8,246,989

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Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA"), Watson Laboratories, Inc. – Florida, Ranbaxy, Inc., and Ranbaxy Laboratories Ltd. (collectively "defendants") submit this brief responding to Warner Chilcott's opening brief concerning the meaning of certain claim terms in U.S. Patents 7,645,459 ("the '459 patent"), 7,645,460 ("the '460 patent"), and 8,246,989 ("the '989 patent") (collectively "the patents in suit").

I. ANALYSIS OF DISPUTED CLAIM TERMS

A. "Pharmaceutically Effective Absorption" ('459 and '460 Patent Claims)

Warner Chilcott urges the Court to adopt the following entire paragraph of the specification as the definition of "pharmaceutically effective absorption":

> The term "pharmaceutically effective absorption" as used herein means an amount of a chelating compound high enough to significantly bind the metal ions and minerals in food but low enough not to significantly alter absorption of the bisphosphonate as compared to absorption in the fasted state. That is, absorption is similar with or without food. Given the high variability of bisphosphonate absorption, fed exposure within about 50% of fasting exposure is expected to be pharmaceutically effective absorption.

(D.I. 110,[1] Ex. A, '459 patent, col. 4, ll. 59–67; Ex. B, '460 patent, col. 4, l. 64–col. 5, l. 5.) This construction should be rejected. While it is true that the paragraph starts off with the words "'pharmaceutically effective absorption' as used herein means . . .", it cannot be the case that the entire paragraph should be

[1] References to D.I. numbers correspond to the docket for Civil Action No. 11-6936.

the definition, as such a construction would leave the definition internally inconsistent and unclear. The paragraph begins by referring to "an amount of a chelating compound" and ends by referring to a level of risedronate absorption the claimed compositions must achieve. As a definition, this paragraph would beg the question of whether "pharmaceutically effective absorption" meant an amount of chelating compound or a level of risedronate absorption.

Warner Chilcott's reason for proffering an unclear construction is tactical: It wants to avoid a precise definition now so it can later argue that the claims are broad enough to ensnare defendants' products, yet narrow enough to avoid the prior art.

There is no legal or factual reason why the Court must saddle this case with such an unclear construction. Warner Chilcott asserts that the law *requires* the Court to adopt the whole paragraph as the definition because: (1) the patent applicant "acted as its own lexicographer" and included the whole paragraph as its definition; and (2) the law requires the Court to adopt the applicant's definition without further inquiry into what the rest of the patent or prosecution history says, and regardless of whether the paragraph constitutes a clear definition. This is wrong for at least two reasons.

First, Warner Chilcott has failed to establish that a person of ordinary skill in the art would have understood the whole paragraph to be the applicant's definition

of "pharmaceutically effective absorption." Warner Chilcott provides only bald attorney argument that this is so, without any expert testimony to support it. Unsubstantiated attorney argument is not competent evidence. *See Invitrogen Corp. v. Clontech Labs., Inc.,* 429 F.3d 1052, 1068 (Fed. Cir. 2005) ("Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony."). Dr. Yates, an expert with many years of experience in the field, has offered the only expert testimony on this issue in the case, and he does not agree with Warner Chilcott's attorneys. As explained in his declaration, it is Dr. Yates's opinion that a person of ordinary skill in the art would have read the patents and prosecution history, and concluded from these and the paragraph's last sentence that the applicant had defined "pharmaceutically effective absorption" as "fed exposure within about 50% of fasting exposure." (Yates Decl. ¶¶ 23–34.)

Second, even if the patent applicant had included the whole paragraph as its definition, the law does not bar the Court from looking at the rest of the intrinsic and extrinsic evidence to resolve inconsistencies and render a clear construction. The opposite is true: While a patent applicant may "act as a lexicographer" and define the terms it uses, a court *must* still construe such definitions in light of the rest of the specification, the claims, the prosecution history and any probative extrinsic evidence, such as expert testimony. *See Phillips v. AWH Corp.*, 415 F.3d

1303, 1314–1318 (Fed. Cir. 2005) (citations omitted). This is especially important where, as here, a proposed definition would leave the meaning of a term unclear. *See Johnson Worldwide Assoc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999) (stating that a situation in which the patentee acts as a lexicographer or a claim term's meaning is unclear, "invites—or indeed, requires—reference to intrinsic, or in some cases extrinsic evidence . . . to determine the scope of the claim language") (citing *Vitronics*); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (discussing the order of addressing intrinsic and extrinsic evidence, and citing *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995) and *Hormone Res. Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1562 (Fed. Cir. 1990) for the proposition that extrinsic evidence may be considered, if necessary). In particular, a court must scrutinize the specification and prosecution history for statements in which the patent applicant *further* explained or narrowed the scope of a defined claim term, since these may clarify or alter the applicant's definition. *See Phillips*, 415 F.3d at 1317. Instead of mechanically adopting the paragraph wholesale, the Court should—indeed must—examine the paragraph *in light of the rest of the intrinsic and probative extrinsic evidence* to determine what "pharmaceutically effective absorption" would have meant to a person of ordinary skill.[2]

[2] The *Teleflex* and *Vitronics* cases cited by Warner Chilcott do not hold that a (continued…)

As explained in defendants' opening brief and Dr. Yates's declaration, the rest of the intrinsic and probative extrinsic evidence makes clear that "pharmaceutically effective absorption" means an amount of absorption of risedronate—fed exposure within about 50% of fasting exposure—and not an amount of EDTA. For example, the patent applicant told the PTO during prosecution that "pharmaceutically effective absorption" means "fed exposure within about 50% of fasting exposure":

> Claim 1 has been amended to recite oral dosage forms having pharmaceutically effective absorption. Support for this amendment is at page 6 of the present specification; *oral dosage forms having pharmaceutically effective absorption exhibit fed exposure within about 50% of fasting exposure*.

(D.I. 110, Ex. D., '459 patent file wrapper, Amendment, at 7 (June 1, 2009) (WTS0006708) (emphasis added); *see also id.* at 8 (WTS00006709); *see also* Ex. E., '460 patent file wrapper, Amendment, at 7–8 (June 1, 2009) (WTS0007497–

Court must don blinders and ignore the rest of the intrinsic and extrinsic evidence whenever a patent applicant attempts to "act as a lexicographer." In fact, the Federal Circuit made clear in both cases that *all* of the probative evidence must still be considered, and if an ambiguity persists, extrinsic evidence may also be considered as needed. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328 (Fed. Cir. 2002) (emphasizing intrinsic evidence, but noting the expert witnesses' testimony as to the ordinary meaning of a term); *Vitronics*, 90 F.3d at 1583. Indeed, the Federal Circuit has stated that "*Vitronics* does not prohibit courts from examining extrinsic evidence [such as expert testimony], even when the patent document is itself clear." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999).

98).) Further, the patent specification and the Burgio declaration submitted to the examiner use the term "pharmaceutically effective absorption" to refer to absorption of the risedronate active ingredient in the fed versus fasted states. (*See, e.g.*, D.I. 110, Ex. A, '459 patent at Abstract; col. 1, ll. 22–23; col. 3, l. 27; col. 3, ll. 53–54; *see also* Ex. B.,'460 patent at Abstract; col. 1, ll. 22–23; col. 3, ll. 26–27; col. 3, ll. 52–53; Ex. D., '459 patent file wrapper, Burgio Decl. at 10, 13, 16, 17 (May 29, 2009) (WTS0006754, 6757, 6760, 6761); Ex. E., '460 patent file wrapper, Burgio Decl. at 10, 13, 16, 17 (May 29, 2009) (WTS0007482, 7485, 7488, 7489.)

A construction that equates "pharmaceutically effective absorption" with an amount of EDTA also would be inconsistent with the claims. The claimed "oral dosage forms having pharmaceutically effective absorption" contain three additional elements: (a) an amount of risedronate; (b) an amount of EDTA; and (c) a "delayed release mechanism" that is not specific as to the exact place, rate or way in which the risedronate and EDTA are released into the lower GI tract. A person of ordinary skill would have understood that whether or not a particular embodiment produces fed exposure within about 50% of fasted exposure depends on each of these variables, not just the amount of EDTA. (Yates Decl. ¶¶ 31–33.) In fact, the specification teaches that "delayed release mechanisms" which produce slow or prolonged release of the risedronate and EDTA in the lower GI tract "will

not overcome the food effect," i.e., will not produce pharmaceutically effective absorption. (D.I. 110, Ex. B., '460 Patent, col. 7, l. 51–col. 8, l. 3.) A person of ordinary skill would have understood that "pharmaceutically effective absorption" referred to a property that the entire formulation must produce when administered to a patient, not an amount of EDTA. (Yates Decl. ¶¶ 31–33.)

Moreover, if "an oral dosage form having pharmaceutically effective absorption" meant an oral dosage form having a specific amount of EDTA, then element (b) of the claims, which provides specific amounts of EDTA, would be superfluous. This would be contrary to the presumption that every term in a claim is meaningful. (*Id.* ¶ 31.)

Warner Chilcott not only fails to provide any expert opinion concerning how a person of ordinary skill in the art would understand the above intrinsic evidence, it ignores the evidence entirely.[3] Apart from the unnecessary lack of clarity that it would inject into the case, Warner Chilcott's proposed definition should be rejected because it is unsubstantiated.

[3] This is so despite the fact that defendants identified all of the intrinsic and extrinsic evidence they intended to rely on in their Local Patent Rule claim construction submissions.

B. "Oral Dosage Form" ('989 Patent Claims)

1. Warner Chilcott's Construction Is Inconsistent With Vital Portions of the Intrinsic Evidence and Is Unsupported by Expert Testimony

Warner Chilcott says that its proposed construction of "oral dosage form" in the '989 patent is "mandated by the intrinsic evidence" because the specification states that "oral dosage form" means "any pharmaceutical composition intended to be administered to the lower gastrointestinal tract of a human or other mammal via the mouth of said human or other mammal." D.I. 109-11, WC Op. Br. 17. Warner Chilcott ignores, however, that the "pharmaceutical composition" in this statement *is further defined* in the specification as "an oral dosage form comprised of a safe and effective amount of [risedronate] and one or more pharmaceutically-acceptable excipients including at least one chelating agent [such as EDTA]." D.I. 110-2, Defs. Op. Br. 25–26. In turn, a "safe and effective amount of a chelating agent" is described as an amount that avoids the food effect, i.e., the effect of residual metal ions from food in the GI tract on absorption of risedronate. *Id*. at 26. The specification also states that the "oral dosage forms" of the claims must produce "pharmaceutically effective absorption of the [risedronate] with or without food or beverages." *Id*.

These related statements provide additional meaning for the term "oral dosage form" in the '989 patent, and make clear that the claimed "oral dosage

forms" are limited to those that produce "pharmaceutically effective absorption." Again, a Court should consider *all* of the relevant intrinsic and necessary extrinsic evidence when construing a claim term. *See Pitney Bowes*, 182 F.3d at 1308.

Although Warner Chilcott complains that defendants' proposed definition "read[s] additional limitations into the claims," this is not true. "Oral dosage form" appears as a limitation in all of the claims of the '989 patent, and all defendants have done is construe that term as it is used in the '989 patent. The parties simply disagree as to how that limitation should be construed.

Warner Chilcott's construction cannot be correct because it would broaden the claims to cover formulations that do not produce "pharmaceutically effective absorption." This is contrary to the specification and prosecution history, which describe "pharmaceutically effective absorption" as a mandatory, essential feature of the alleged invention, and not merely an optional feature or preferred embodiment. The patent teaches that "pharmaceutically effective absorption" is what enables the claimed compositions to be administered without regard to food or beverage intake, which is the very feature that the patent applicant asserted distinguished the invention over the prior art. Claims should be construed so as to include features that the intrinsic evidence describes as necessary, or as distinguishing the claims from the prior art. *See*, *e.g.*, *MBO Labs, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007) (stating that where the

patentee clearly indicated in the specification and the prosecution history that the invention contained an essential feature, it is "appropriate to construe the claims so as to ensure that they, too, require that feature."); *Edwards Lifesciences LLC v. Cook, Inc.*, 582 F.3d 1322, 1330, 1333 (Fed. Cir. 2009); *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1317–1318 (Fed. Cir. 2007).

Warner Chilcott attempts to sidestep the importance of "pharmaceutically effective absorption" to the alleged invention by arguing that this is actually an inherent property of the formulations claimed in the '989 patent. According to Warner Chilcott, formulations that contain 35 mg of a "risedronate salt" and 100 mg of "EDTA or a pharmaceutically acceptable salt" inherently produce "pharmaceutically effective absorption." Warner Chilcott presents no expert testimony or other competent evidence that this is so, however, or that a person of ordinary skill in the art would have concluded as much from the specification. Again, attorney argument is not sufficient to establish Warner Chilcott's view of the scientific facts. *See Invitrogen Corp. v. Clontech Labs., Inc.,* 429 F.3d 1052, 1068 (Fed. Cir. 2005)

The only expert testimony in the case on this issue establishes that Warner Chilcott's attorney argument is wrong. It is Dr. Yates's opinion that a person of ordinary skill would *not* have concluded from the specification that every delayed-release formulation of 35 mg of risedronate salt and 100 mg of EDTA or a

pharmaceutically acceptable salt will produce "pharmaceutically effective absorption." (Yates Decl. ¶ 38; Patunas Resp. Decl.,[4] Ex. I, Yates Dep. Tr. 198:17–200:25; 205:12–206:17 (stating that "[a] composition could have 100 milligrams or more of EDTA and still fail. . . . [T]he amount of EDTA does not ensure pharmaceutically effective absorption.") As explained, the patents teach that the rate, site and manner in which the risedronate and EDTA are released will also determine whether the oral dosage form produces "pharmaceutically effective absorption." (Yates Decl. ¶ 38.) The particular acid or salt forms of risedronate and EDTA employed may also impact absorption. (*See* Patunas Resp. Decl., Ex. I at 299:14–300:4.) A person of ordinary skill would have understood that oral dosage forms which do not produce "pharmaceutically effective absorption" fall outside of the claims, because according to the patent they cannot be administered without regard to food or beverage intake.

In fact, Warner Chilcott's exclusion of "pharmaceutically effective absorption" from the claims would render them invalid, since the claims would be broader than the supporting disclosure of the patent. Defs. Op. Br. 22–23.

[4] Exhibits in the Declaration of Michael E. Patunas in Support of Defendants' Responding Brief in Further Support of Their Proposed Claim Constructions bear exhibit letters that continue from the exhibits in the Declaration of Michael E. Patunas in Support of Defendants' Opening Brief in Support of Their Proposed Claim Constructions (D.I. 110).

2. Defendants' Construction Does Not Render Any Term In the '989 Patent Claims Superfluous

Warner Chilcott incorrectly argues that "oral dosage form" in the '989 patent cannot be limited to those that only produce "pharmaceutically effective absorption" because it would render superfluous the phrase "pharmaceutically effective absorption" in the '459 and '460 patents, which claim "oral dosage form[s] having pharmaceutically effective absorption." WC Op. Br. 18. Defendants' construction of "oral dosage form" in the '989 patent does not render any terms superfluous because it applies only to the '989 patent claims. The alleged redundancy in the '459 and '460 patents would occur only if "oral dosage form" were construed the same way for all three patents. Where, as here, the evidence shows that the same term should be construed somewhat differently in a separate but related patent, such a construction is appropriate. *See*, *e.g.*, *Edwards*, 582 F.3d at 1333.

Moreover, even if Warner Chilcott is correct, a court should not discard the most reasonable construction in light of the intrinsic evidence solely because it creates some redundancy. *See id.* at 1330 (stating that "[e]ven if the claim construction had rendered the dependent claim redundant, the doctrine of claim differentiation does not require us to give [the potentially broader term its] broadest possible meaning"). As defendants have pointed out, a claim construction that gives meaning to every term in a claim is preferred to one that renders terms

redundant. This preference is not a bright-line rule, however, as "[d]ifferent terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper." *See*, *e.g.*, *Edwards*, 582 F.3d at 1330, 1333 (affirming the district court holdings that the terms "graft" and "intraluminal graft" were both limited to grafts that were intraluminal, and "wires" and "malleable wires" were both limited to wires that were malleable).

Warner Chilcott's redundancy argument also incorrectly assumes that the patent applicant "made clear" to the examiner that the "oral dosage form" of the '989 patent was broader than the "oral dosage form having pharmaceutically effective absorption" of the '459 and '460 patents. The prosecution history does not support this. The applicant added "pharmaceutically effective absorption" to the claims of the '459 and '460 patents by amendment in order to distinguish it from prior art that the examiner cited in an obviousness rejection. After adding "pharmaceutically effective absorption" to overcome the examiner's obviousness rejection, and after the examiner had allowed the amended '459 and '460 patent claims, the applicant prosecuted the '989 patent *to the same examiner*. When the applicant presented claims to "oral dosage forms," it did not inform the examiner that the claims were no longer limited to formulations that produce "pharmaceutically effective absorption." (D.I. 110, Ex. F, '989 patent file

wrapper, Response (Jan. 17, 2012) (WTS0010077–83).) Had the applicant done so, the examiner presumably would have rejected the claims over the same prior art as in the '459 and '460 applications.

In a similar case, the Federal Circuit determined that the examiner must have considered the claims to be of the same scope and not broader. In *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1317–1318 (Fed. Cir. 2007), the examiner allowed Hakim's claims to a cup having a "slit" because the slit "distinguish[ed] all of the claims from the cited [prior art] references." *Id.* at 1316. Hakim later filed a continuation application with claims that included the term "opening" instead of "slit," and included a letter from his attorney stating that Hakim was broadening the claims. *Id*. Hakim did not, however, "inform the examiner that the previous disclaimer, and the prior art it was meant to avoid, may need to be revisited." *Id.* at 1318. Given the examiner's earlier rejections in the parent application, the Federal Circuit inferred that the examiner must have viewed the later claims as being of the same scope or would have rejected them over the same prior art. *Id.*

A similar inference is warranted here. The applicant overcame the examiner's prior art rejections in the '459 and '460 patents by amending its claims

to require "pharmaceutically effective absorption."[5] The applicant did not tell the examiner that it was removing the limitation from the '989 patent claims and thus the prior art should be revisited. The Court should infer that the examiner regarded the "oral dosage forms" of the '989 patent claims as also being limited to those that produce "pharmaceutically effective absorption."

C. "EDTA" ('459 and '460 Patent Claims) and "EDTA or a Pharmaceutically Acceptable Salt Thereof" ('989 Patent Claims)

"EDTA" is a shorthand abbreviation for the name of a molecule and has a plain and customary meaning to a skilled person: "ethylenediamine tetraacetic acid its salts." (Elder Decl. ¶¶ 24–25.) Warner Chilcott has not introduced any expert testimony to the contrary. Since the patents in suit do not define "EDTA" or describe it in a manner inconsistent with that plain meaning, the term should be

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[5] In remarks accompanying the amendment, the applicant emphasized that this amendment distinguished the claims from the prior art:

> In contrast [to the prior art references cited by the examiner], Applicants have surprisingly discovered oral bisphosphonate compositions that address the food effect, while maintaining *pharmaceutically effective absorption*. As such, the inventors have discovered oral bisphosphonate compositions that have minimized the food effect, while maintaining pharmaceutically acceptable absorption, regardless of whether the patient is in a fasted state, the current per label state (e.g., taking the composition 30 minutes prior to any food or drink), or the fed state.

(Ex. D., '459 patent file wrapper, Amendment, at 14 (June 1, 2009) (WTS0006715) (emphasis added); *see also* Ex. E., '460 patent file wrapper, Amendment, at 12 (WTS0007502).)

construed to have that meaning. In fact, the parties agree that "EDTA" should be defined as "ethylenediamine tetraacetic acid its salts" (or "pharmaceutically acceptable salts" in the case of the '989 patent claims).

Warner Chilcott proposes to add the phrase "the chelating agent" to this otherwise agreed-upon definition, however, and makes clear in its brief that its purpose for doing so is to narrow the claim term with a functional limitation. Warner Chilcott wants to construe the term more narrowly than the plain meaning in order to avoid certain prior art. Contrary to Warner Chilcott's position, the intrinsic evidence does not "mandate" that EDTA be limited to particular salts (or pharmaceutically acceptable salts) capable of performing the chelating function. As explained in defendants' opening brief, the specification does not exclude *any* salts of EDTA, and the prosecution history makes clear that any salt (or pharmaceutically acceptable salt) of ethylenediaminetertaacetic acid is included within the term "EDTA." Defs. Op. Br. 28–31. In fact, the prosecution history shows that the applicant removed the term "chelating agent" from the claims during prosecution of the '459 and '460 patents in order to obtain their allowance. *Id*. at 30–31. Nothing in the intrinsic evidence requires undoing this prosecution choice.[6]

[6] The fact that defendants' proposed constructions of other parts of the claims use the words "chelating agent" does not support Warner Chilcott's position. The (continued…)

D. "Delayed Release Mechanism" ('459 and '989 Patent Claims) and "Delayed Release Mechanism to Immediately Release the Risedronate" ('460 Patent Claims)

Warner Chilcott's brief makes clear that the dispute concerning the terms "delayed release mechanism" in the claims of the '459 and '989 patents, and "delayed release mechanism to immediately release the risedronate" in the '460 patent, boils down to Warner Chilcott's desire to have Enterion capsules encompassed by those terms. WC Op. Br. 11. This is yet another construction advanced by Warner Chilcott in the hope that it can avoid invalidating prior art.

A person of ordinary skill would not have understood that a mechanical laboratory appartatus like the Enterion capsule includes a "delayed release mechanism" as defined in the patents. As explained in defendants' opening brief, the specifications state that the "delayed release" of the claims is achieved by "formulating the pharmaceutical composition." "Formulating" is a term of art that means combining active ingredients and excipients together to form a pharmaceutical drug product. Defs. Op. Br. 33; (Elder Decl. ¶ 32). In contrast, an

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constructions use the term "chelating agent" instead of "EDTA" because the specifications state that classes of chelating compounds other than EDTA can be employed in the alleged invention, including hydroxycarboxylic acids, polyphosphates, and dozens of other chemical compounds. *See* '989 patent, col. 8, ll. 29-63. This does not alter the fact that when the patent applicant limited the claims to one class, EDTA, it did so without limiting the kinds of EDTA salts included within the term. If the Court believes it would avoid confusion, defendants are willing to replace "chelating agent" with "EDTA" in all of their proposed constructions.

Enterion capsule is a remote-controlled, robotic laboratory apparatus used to test the results of releasing drugs and excipients at various points in the GI tract. (Patunas Resp. Decl. Ex. J., I. Wilding *et. al.*, *Development of a New Engineering-Based Capsule for Human Drug Absorption Studies*, 3 PHARM. SCI. & TECH. TODAY 385, 388–391 & fig.4 (Nov. 2000).) It is undisputed that the timing of release from an Enterion capsule is not controlled by formulation excipients, but by a remote-controlled device operated by a lab technician. It is not intended for treating disease, nor has it ever been marketed as a pharmaceutical drug product. (Elder Decl. ¶ 38.) Given that it requires complex lab equipment and technicians to operate,[7] it would be entirely impractical to use it as a pharmaceutical product.

Warner Chilcott misleadingly asserts that "one of the priority applications to the '460 patent describes use of an Enterion capsule." WC Op. Br. 11. It does not describe use of the Enterion capsule as a pharmaceutical oral dosage form to be used to treat patients for bone disease. It refers to hypothetical experiments using Enterion capsules that, if performed, would provide data concerning the degree to which EDTA increased the absorption of risedronate under various experimental conditions and at various sites in the GI tract. (D.I. 109-8, Ex.6, U.S. Provisional

[7] The equipment includes a gamma scintigraphy camera, which is used to track the Enterion capsule as it traverses the GI tract, and a remote triggering device, which activates a spring-loaded plunger within the capsule to expel its contents when the capsule reaches the desired region of the GI tract. (Patunas Resp. Decl. Ex. J. at 388-389.)

App. No. 60/573,881 at WTS0007620–621 (Example 12).) Such hypothetical science experiments describe a typical laboratory use of Enterion capsules and would not have suggested to a person of ordinary skill in the art that the Enterion apparatus is an embodiment of the claimed oral dosage forms. (Elder Decl. ¶¶ 33–38; Patunas Resp. Decl. Ex. K., Elder Dep. Tr. 159:5–15, 168:9–170:20; 173:3–174:10.)

Moreover, this reference appeared in a preliminary provisional application only; the applicant removed the Enterion references when it filed the applications that issued as the patents in suit, which confirms that the inventors did not regard the "delayed release mechanism" of the inventions as including such lab apparatus. (*See* D.I. 110, Ex. D at WTS0005623–25 (Example XIX) (removing Enterion capsules from the example as it previously appeared as Example 12 in the provisional).)

E. "An Enteric Coating Which Provides For Immediate Release" ('460 Patent Claims)

Warner Chilcott's proposed compromise for the definition of "an enteric coating which provides for immediate release" is as follows:

> A coating comprised of one or more polymers designed to dissolve in a pH dependent manner and which effects release of the bisphosphonate and chelating agent in the small intestine in an immediate release fashion, *i.e.*, all of the bisphosphonate and chelating agent will be released from the oral dosage form within 60 minutes when measured by a standard USP dissolution method. An

> enteric coating includes coatings that are insoluble at a pH below pH 5.5, but soluble between about pH 5.5 and about pH 6.5.

This definition is consistent with defendants' proposed construction so long as the phrase "an enteric coating" is understood to provide release at pH values of between 5.5 and 6.5, i.e., pH values in the small intestine, and the phrase "immediate release" is understood to be release in which all of the risedronate and EDTA will be released from the oral dosage form within 60 minutes when measured by a standard USP method. It appears that the parties do not dispute this, and thus Warner Chilcott's compromise is acceptable to defendants.

F. "An Enteric Coating Which Provides For Release" ('459 Patent Claims) and "pH Dependent Enteric Coating" ('989 Patent Claims)

The dispute here boils down to whether the term "enteric coating" means a coating that begins to release the active ingredients in the small intestine, or whether release can begin elsewhere. Warner Chilcott proposes a construction that would include coatings "that are insoluble at a pH below pH 5.5, but soluble at pH 5.5 or higher." Defendants agree with that definition to the extent it means that the coatings do not dissolve in the stomach, where the pH is below 5.5, but do begin to dissolve in the small intestine, where the pH is 5.5 or above. Defs. Op. Br. 35–37. Warner Chilcott, however, appears to contend that the coating could be insoluble at a pH higher than 5.5, which does not even fit its own definition. WC Op. Br. at 14–15.

The portion of the specification Warner Chilcott cites does not support its position. That portion states that the small intestine has a pH of 5.5 or above, and that any enteric coating which is soluble at that pH may be used in the invention:

> One embodiment of the present invention is delivered to the lower GI tract utilizing a pH dependent enteric coating material made from a partly methyl esterified methacrylic acid polymer. The oral dosage form can be in the form of an enteric coated compressed tablet made of granules or particles of active ingredient or a gelatin capsule which contains beads or small particles of active ingredient which have themselves been enterically coated.
>
> Any enteric coating which is insoluble at a pH below 5.5 (i.e., that generally found in the mouth, pharynx, esophagus, and stomach), but soluble at pH 5.5 or higher (i.e., that present in the small intestine and the large intestine) can be used in the practice of the present invention. Accordingly, when it is desired to effect delivery of the bisphosphonate and the chelating agent to the small intestine, any enteric coating is suitable which is wholly- or partially-insoluble at a pH below 5.5 and soluble at a pH 5.5 or above.

(D.I. 110, Ex. C., '989 patent, col. 11, l. 53–col. 12, l. 2.)

The plain meaning of enteric coating as understood by a person of ordinary skill in the art is that release takes place—at least in part—in the small intestine. (Elder Decl. ¶ 45). Warner Chilcott has presented no expert testimony or other evidence to contradict that meaning. Therefore, "enteric coating" in these terms should be construed as defendants contend—"a pH-dependent coating that will dissolve and begin to release active ingredient once the dosage form has reached the small intestine." In the alternative, defendants accept Warner Chilcott's

definition as long as it is understood that the term describes coatings that are soluble in the small intestine, i.e., that are soluble at a pH of 5.5 or above.

G. "pH Dependent Enteric Coating of the Granules" ('989 Patent Claims)

The only disagreement the parties have concerning the construction of "pH dependent enteric coating of the granules" is whether the phrase covers enteric-coated tablets or capsules made from uncoated granules, as Warner Chilcott contends, or granules that are enteric-coated before they are incorporated into a tablet or capsule, as defendants contend.

The claims and specification make clear that defendants' definition is correct. Defs. Op. Br. 39–40. Indeed, the first portion of the specification that Warner Chilcott cites undermines its proposed definition. It contrasts coated tablets made uncoated, compressed granules with capsules containing granules that have been coated:

> The oral dosage form can be in the form of an enteric coated compressed tablet made of granules or particles of active ingredient or a gelatin capsule which contains beads or *small particles of active ingredient which have themselves been enterically coated*.

WC Op. Br. 20 (citing '989 patent, col. 11, ll. 56–60) (emphasis added).

The difference between claim 3 and claim 15 also demonstrates that Warner Chilcott's construction is incorrect. Claim 3 narrows claims 1 and 2 to enteric-coated tablets:

> 1. An oral dosage form comprising:
>
> (a) about 35 mg of a risedronate salt;
> (b) about 100 mg of EDTA or a pharmaceutically acceptable salt thereof; and
> (c) a delayed release mechanism to deliver the risedronate salt and EDTA or pharmaceutically acceptable salt thereof to the lower GI tract.
>
> 2. The oral dosage form of claim 1, wherein the oral dosage form is *a tablet* comprising a core containing the risedronate salt and EDTA or pharmaceutically acceptable salt thereof.
>
> 3. The oral dosage form of claim 2, wherein the delayed release mechanism is a pH dependent enteric coating.

(emphasis added). In contrast, claim 15 narrows claim 1 to enteric-coated granules:

> 15. The oral dosage form of claim 1, wherein the oral dosage is comprised of granules comprised of the risedronate salt and EDTA or pharmaceutically acceptable salt thereof, and wherein the delayed release mechanism is a *pH dependent enteric coating of the granules*.

Thus, the claims draw a distinction between oral dosage forms made of coated tablets, and oral dosage forms made of coated granules.

The remaining portions of the specification that Warner Chilcott cites simply explain that the enteric-coated tablets of, e.g., claim 3, can include tablets made from compressed granules of risedronate and EDTA. Those portions do not say the tablets are made of enteric-coated granules to which a second, redundant enteric coating is applied. Defendants' proposed construction is more consistent with the intrinsic evidence and thus the Court should adopt it.

II. CONCLUSION

For the foregoing reasons, and those set forth in their opening brief, defendants respectfully request that the Court adopt their proposed constructions of the disputed terms.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 11th day of January, 2013, I caused copies of the foregoing *Defendants' Responding Brief in Further Support of Their Proposed Claim Constructions for U.S. Patent Nos. 7,645,459, 7,645,460, and 8,246,989* to be served upon the following by electronic mail:

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